K011564
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510 K SUMMARY

DESCRIPTION OF DEVICE

The Neolead is a self-adhesive, disposeable sensor, which receives electrical impulses from the body in a non-invasive manner. These impulses are then transmitted to a monitor, which displays the electrographic patterns of cardiac activity. Hydrogel is the pectin based conductive material between the skin and the sensor. Hydrocolloid is the pectin based adhesive.

INTENDED USE OF THE DEVICE

Neoleads are designed as a desposeable, self-adhesive **sensor** to be placed on the skin of the newborn and pediatric patient in order to gather, transmit and record cardiac electrical activity.

TECHNICAL CHARACTERISTICS

The Neolead is equivalent to legally marketed electrodes in the marketplace now. The addition of the hydrocolloid as the adhesive is based on the recommendations of the Neonatal Nurses National Association guidelines as well as a long history of its skin friendly properties.

SUBSTANTIAL EQUIVLENCE

The Neolead is substantially equivalent to the following predicated electrodes

Kittycat-Kendall-LTP
Neotrode-ConMe Corp
Klear-Trace-CAS Medical Systems, Inc
SilveReez-Clinimark
H/P –HewlettPackard

The Hydrocolloid adhesive used with the Neolead is substantially equivalent to the Hydrocolloid in other Neotech predicated devices.

NeoBar	NeoSmile
NeoBridge	NeoHold
NeoShades	NeoBond

ELECTRICAL PERFORMANCE SUMMARY

The Neoleads meet the basic performance standards (3.2.2.1 AC Impedance, 3.2.2.2 DC Offset Voltage, 3.2.2.3 Combined Offset Instability and Internal Noise, 3.2.2.4 Defibrillation Overload Recovery, 3.2.2.5 Bias Current Tolerance) of the AAMI for Disposable ECG Electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 3 2002

Arnold M. Heyman, M.D.
Neotech Products, Inc.
9135-F Alabama Ave.
Chatsworth, CA 91311

Re: K011564
Trade Name: NeoLead
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: Not Dated
Received: October 5, 2001

Dear Dr. Heyman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indication for Use

The NeoLead Hydrocolloid/ Hydrogel electrode is intended to be used for resting ECG monitoring on neonatal and pediatric patients in a hospital setting.

Division of Cardiovascular & Respiratory Devices
510(k) Number K018264

Prescription Use ✓
(Per 21 CFR 801.109)